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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,598	02/28/2002	Shinji Shimizu	2109-24	3579

7590 09/22/2004

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8th Floor
1100 North Glebe Road
Arlington, VA 22201-4714

EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MS

Office Action Summary

Application No.

10/069,598

Applicant(s)

SHIMIZU ET AL.

Examiner

Emily Le

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4 and 19-24, drawn to a material for use in extracorporeal circulation comprising a water-insoluble carrier immobilized a peptide thereto, wherein the peptide has part or all of the receptor amino acid sequence as set forth in SEQ ID NO: 1; and a removal unit for a diabetic complication factor.

Group II, claim(s) 5-7, drawn to a material for use in extracorporeal circulation comprising a water-insoluble carrier immobilized thereto an antibody.

Group III, claim(s) 8-18, drawn to an adsorbent for a diabetic complication factor comprising a water-insoluble carrier immobilized a ligand thereto.

Group IV, claim(s) 25-26, drawn to a method for removing a diabetic complication factor wherein a fluid to be treated is brought into contact with the unit housed with the material or the adsorbent.

2. The inventions listed as Groups I and IV, and II-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I is directed to a composition that comprising a water-insoluble carrier immobilized a peptide thereto; and a removal unit for a diabetic complication factor.

The invention of Group II is directed to a material for use in extracorporeal circulation comprising a water-insoluble carrier immobilized thereto an antibody. This composition is different from that of the composition of Group I. An antibody is different from a peptide. An antibody has the basic structure of two light and two heavy chains, and can be found as dimers, trimers, or pentamers. This structure is different from that of a peptide. A peptide does not have the same structure as an antibody. Therefore, a peptide lacks significant, at least, structural similarity to an antibody. Hence, a composition that comprises a peptide lacks unity with a composition that comprises an antibody.

The invention of Group III also lacks unity with the inventions of Groups I-II. The invention of Group III is directed to an adsorbent for a diabetic complication factor comprising a water-insoluble carrier immobilized a ligand thereto. According to Stedman's Medical Dictionary, 5th Edition, a ligand is any individual atom, group, or molecule attached to a central metal ion by multiple coordinate bonds. This structural description of a ligand is different from that of a peptide and an antibody. Therefore, a ligand lacks significant structural similarity to a peptide and an antibody. Hence, a composition that comprises a ligand lacks unity with composition that comprises a peptide or an antibody.

The invention of Group I and II are related as a composition and its first method of use. However, these two inventions lack unity with one another because the shared technical feature does not provide a contribution over the prior art, thereby rendering a lack of special technical feature. The shared technical feature that is shared between

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the inventions is a composition comprising a water-insoluble carrier immobilized a peptide thereto, wherein the peptide has part or all of the receptor amino acid sequence as set forth in SEQ ID NO: 1. However, this shared technical feature does not provide a contribution over the prior art in view of Hirai et al., U.S. Patent No. 6037458, field 09/1992. Hirai et al. teaches of composition for a protein, which comprises a water-insoluble carrier. The protein of Hirai et al. comprises at least one amino acid that is part of SEQ ID NO: 1, because SEQ ID NO: 1 consists of all twenty amino acids. Therefore, in view of Hirai et al. the technical feature shared by both inventions does not provide a contribution over the prior art. Hence, the inventions lack unity with one another.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

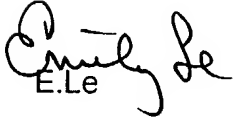
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

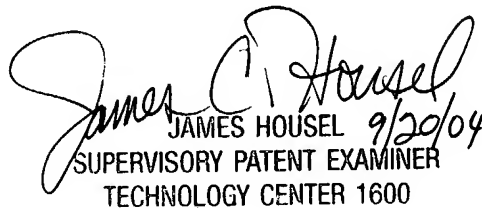
The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


E. Le


JAMES HOUSEL 9/20/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600